

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS
CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

Redacted - Public Version

C.A. No. 23-975 (RGA) (SRF)

[REDACTED]

**DEFENDANT’S MOTION *IN LIMINE* REGARDING IMPROVEMENTS IN “FORCED
VITAL CAPACITY” RECITED IN CLAIMS 9 AND 10 OF THE ’327 PATENT**

Table of Exhibits

Exhibit #	Description
A	Excerpts of March 28, 2025 deposition transcript of Dr. Steven Nathan
B	Excerpts of Dr. Bradley Wertheim Rebuttal Report dated January 23, 2025
C	May 2, 2025 email to UTC regarding meet-and-confer

The inconsistent positions of UTC's experts regarding the scope of the term "forced vital capacity" ("FVC") in claims 9-10 of the '327 patent are confusing, unduly prejudicial to Liquidia, likely to cause delay, and will waste both the Court's and the parties' time at trial. Dr. Wertheim's opinion regarding this issue is also not based on sufficient facts or data and does not reflect a reliable application of principles and methods to the facts of the case. Thus, evidence and argument on the inconsistent opinions expressed by UTC's experts regarding the scope of the claim term FVC should be excluded under Federal Rules of Evidence 403 and 702.

UTC expert Dr. Nathan testified that the claim term FVC in claim 9 encompasses both absolute and percent predicted FVC. *See* Ex. A, 122:14-123:15 (testifying that "by virtue of the fact that [the language of claims 9-10] doesn't specify absolute or percent, I would read it to include either one of those or both."). Dr. Nathan's testimony is consistent with the language of claim 10, which depends from claim 9 and is directed to absolute FVC (measured in "ml"). *See* D.I. 8-2 ('327 patent), cl. 10; Ex. A, 126:4-10 (testifying that "a 20 ml improvement in forced vital capacity" is "an improvement in absolute forced vital capacity."). It is also consistent with Example 1 in the '327 patent's specification, which reports "FVC suggestive data" in **both** absolute (in ml) and percent predicted FVC. *See* D.I. 8-2, 22:51-67; *see also id.*, Tables 1-3 (presenting results of "Analysis of FVC Data Using Mixed Model Repeated Measurement" in both absolute and percent predicted FVC); *id.*, 25:44-62 (Example 2 discussing "[c]hange from baseline to Week 24 of treatment in FVC" in both absolute and percent predicted FVC).

In contrast to Dr. Nathan, Dr. Wertheim expressly takes the position that the claim term FVC in claim 9 does not encompass both percent predicted and absolute FVC. *See* Ex. B, ¶381 ("I disagree with Dr. Channick that claims 9 and 10 of the '327 patent lack written description if the specification does not disclose statistically significant improvements in **both** absolute FVC and

percent predicted FVC”) (emphasis in original). Dr. Wertheim adds that “a POSA would understand that (i) absolute FVC and percent predicted FVC are two different expressions of the same underlying data; and (ii) percent predicted FVC is far more useful in the context of a large clinical trial like INCREASE.” *Id.* Dr. Wertheim does not provide any justification or explanation for this opinion nor does he consider that his position is inconsistent with Dr. Nathan’s, the ’327 patent specification, and claims 9-10 themselves, as explained above. *Id.* In fact, Dr. Nathan offered the opposite opinion stating that “[a]bsolute [FVC] is more valid” than percent predicted FVC. *See* Ex. A, 59:1-22.

The issue of whether the claim term FVC encompasses both percent predicted and absolute FVC is highly relevant to Liquidia’s non-infringement and invalidity theories in that it would, for example, influence Liquidia’s choice of prior art references used to prove invalidity.

This issue also remains a point of contention between the parties because UTC’s attorneys have apparently adopted Dr. Wertheim’s position. During the parties’ meet-and-confer on May 2, 2025, UTC was unwilling to resolve this issue by confirming that the claim term FVC in claims 9-10 encompasses both absolute and percent predicted FVC. *See* Ex. C (May 2, 2025 Liquidia email to UTC regarding meet-and-confer).

Federal Rule of Evidence 403 provides that “[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, ... undue delay, wasting time[.]” FED. RULE. EVID. 403. This Court has “exercised its discretion to exclude both evidence and argument” where there is a strong likelihood of issue confusion. *Edwards Lifesciences LLC v. Medtronic CoreValve LLC*, 2014 WL 12927825, at *1 (D. Del. Jan. 2, 2014); *see also Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, 2018 WL 2186677, at *1 (D. Del. May 11, 2018) (excluding evidence and arguments

related to the Court’s pre-trial rulings because it would “be unfairly prejudicial, confusing, and waste time[.]”); *Cirba Inc. v. VMware, Inc.*, 2023 WL 3190781, at *10 (D. Del. Apr. 24, 2023). This Court has also excluded expert opinion not relying on “sufficient facts or data” under Federal Rule of Evidence 702. *See Cirba Inc. v. VMware, Inc.*, 2023 WL 3151853, at *2 (D. Del. Apr. 18, 2023) (excluding expert’s “opinions regarding noninfringement and invalidity” because they were “not based on sufficient facts or data using reliable principles and methods”); *see also Manufacturing Res. Int’l, Inc. v. Civiq Smartscapes, LLC*, 2019 WL 4198194, at *5 (D. Del. Sept. 4, 2019); *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 2013 WL 936449, at *5 (D. Del. Mar. 11, 2013).

Dr. Nathan’s and Dr. Wertheim’s inconsistent positions on whether the claim term FVC in claim 9 includes both percent predicted and absolute FVC is confusing and unduly prejudices Liquidia as it leaves Liquidia to guess as to what UTC’s experts will put forward regarding FVC and thereby requires Liquidia to offer alternate theories of lack of written description and invalidity based on prior art. Accordingly, the inconsistent positions are likely to cause delay and waste the Court’s time. Dr. Wertheim also does not provide any explanation as to why FVC does not encompass both percent predicted and absolute FVC—he clearly did not consider the ’327 patent claim, the fact that claim 10 depends on claim 9, and the specification—all of which contradict Dr. Wertheim’s position. Finally, this is not an issue of claim construction as UTC may suggest, but instead an issue of prejudice and confusion based on inconsistent positions regarding the same FVC term by UTC’s experts.

For the reasons above, Liquidia respectfully requests that the Court exclude any argument or opinion that the claim term FVC in claim 9 encompasses only percent predicted FVC.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED THERAPEUTICS
CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

C.A. No. 23-00975-RGA-SRF



**OPPOSITION TO DEFENDANT’S MOTION *IN LIMINE* REGARDING
IMPROVEMENTS IN “FORCED VITAL CAPACITY” RECITED IN
CLAIMS 9 AND 10 OF THE ’327 PATENT**

Table of Exhibits

A	<i>Natera, Inc. v. ArcherDX, Inc.</i> , C.A. No. 20-125, D.I. 585 (D. Del. May 3, 2023)
B	2025-01-23 Rebuttal Expert Report of Bradley M. Wertheim, M.D.
C	2025-03-28 Deposition of Steven Nathan
D	Email from Sanya Sukduang to UTC Counsel (Apr. 4, 2025)
E	Email from Harrison Gunn to Liquidia Counsel (May 2, 2025)

Liquidia’s motion *in limine* regarding forced vital capacity (“Motion”) should be denied. Liquidia’s Motion is procedurally improper because it: (i) exceeds the limit on motions *in limine* (“MILs”); (ii) is duplicative of a pending *Daubert* motion; and (iii) improperly seeks claim construction. Further, the Motion fails on the merits because it misconstrues the opinions and testimony of UTC’s experts in an effort to allege inconsistency and prejudice that does not exist.

Limit on MILs. The Scheduling Order in this action permits each party to file three MILs. D.I. 45, ¶ 13. Liquidia met this limit when it filed three *Daubert* motions each of which expressly requested that the Court also consider them as MILs under FRE 402 and/or 403. *See, e.g.*, D.I. 279, at 18; D.I. 281, at 19; D.I. 283, at 7 n.2. Liquidia’s latest MILs (putting Liquidia at a total of *five*) should be denied because they facially violate the Scheduling Order. *See Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125-GBW, D.I. 585, at 4 (D. Del. May 3, 2023) (Ex. A); *Datacore Software Corp. v. Scale Computing, Inc.*, 2024 WL 3823001, at *2 (D. Del. Aug. 14, 2024).

Duplicative of *Daubert*. Liquidia’s Motion is also duplicative of its pending *Daubert* challenge to Dr. Wertheim, which similarly seeks to exclude opinions regarding forced vital capacity (“FVC”). *See* D.I. 281, at 15-18. Indeed, Liquidia’s opening paragraph explicitly invokes FRE 702, asserting that Dr. Wertheim’s opinion is “not based on sufficient facts or data and does not reflect a reliable application of principles and methods to the facts of the case.” Motion at 1. Liquidia’s repeated citation to *Daubert* caselaw, as opposed to MIL precedents, evidences its improper attempt to supplement its existing *Daubert* challenge to Dr. Wertheim. Motion at 2-3.

Claim Construction. Further, Liquidia’s Motion improperly seeks construction of a term that was never raised during *Markman*. Liquidia identifies the “issue” here as “whether the claim term FVC encompasses both percent predicted and absolute FVC” and later “requests that the Court exclude any argument or opinion that the claim term FVC in claim 9 encompasses only

percent predicted FVC.” Motion at 2, 3. Thus, Liquidia’s Motion invites the Court to adjudicate what “FVC” means in the context of claim 9. This term, however, was never raised during *Markman* proceedings in this matter and has never been construed by the Court. A MIL is not the proper vehicle to raise novel claim construction issues on the eve of trial. *See Nox Med. Ehf v. Natus Neurology Inc.*, 2018 WL 3382915, at *1 (D. Del. Apr. 26, 2018); *Cadence Pharms., Inc. v. Innopharma Licensing LLC*, 2017 WL 39560, at *1 (D. Del. Jan. 4, 2017).

Substantively Wrong. Procedural defects aside, Liquidia’s Motion fails on the merits. Liquidia argues that UTC’s clinical experts have offered “inconsistent” testimony regarding the meaning of “forced vital capacity.” Motion at 3. This assertion is false and is based on a fundamental misreading of the opinions and deposition testimony of Drs. Nathan and Wertheim.

At the outset, Liquidia asserts that “Dr. Wertheim expressly takes the position that the claim term FVC in claim 9 does not encompass both percent predicted and absolute FVC.” Motion at 1. Dr. Wertheim has never said this. To the contrary, his Rebuttal Report makes clear that a POSA would understand the term “forced vital capacity” to encompass **both** the absolute and percent predicted expressions of that endpoint—including in the specific context of claim 9. *See, e.g.*, Ex. B, ¶¶ 21, 65-66, 235-36, 315, 322. This is entirely consistent with Dr. Nathan’s testimony. Ex. C, at 122:14-123:15. Notably absent from Liquidia’s Motion is any citation to Dr. Wertheim’s deposition, where Liquidia declined to ask a **single question** regarding the scope of “FVC.” Nonetheless, Liquidia tries to confuse the issue by pointing to Dr. Wertheim’s disagreement with Liquidia’s Dr. Channick that a statistically significant improvement in both expressions of FVC is needed to establish written description for claims 9 and 10. Motion at 1-2 (citing Ex. B at ¶ 381). This disagreement is not about what the term “FVC” means, but whether certain data in the specification support written description. Such disputes are fact issues to be resolved at trial.

Wright v. Elton Corp., 2022 WL 1091280, at *3 (D. Del. Apr. 12, 2022).

The actual target of Liquidia's Motion is Dr. Wertheim's opinion that a POSA would view percent predicted FVC as "preferable" to absolute FVC in the context of the clinical data presented in the '327 patent. *See, e.g.*, Ex. B, ¶¶ 315, 323, 377. Liquidia complains that Dr. Wertheim "does not provide any justification or explanation for this opinion." Motion at 2. But this, again, is false. As Dr. Wertheim has explained: "[a] POSA would also understand change in % predicted value to be the most valuable expression of this endpoint in the context of large clinical trials because it allows patients with varying demographics (e.g., age, sex, height) to be compared against each other on a like-for-like basis." *Id.*, ¶ 315; *see also id.*, ¶¶ 65, 323, 377. Liquidia further suggests that "Dr. Nathan offered the opposite opinion" on this point at his deposition. Motion at 2. However, this ignores the fact that Dr. Nathan's testimony is entirely **consistent** that "the utility of percent predicted is for an individual patient at one point in time, to see where they are in relation to the rest of the population of their similar heart demographics." Ex. C, at 59:8-22. Liquidia's criticisms of Dr. Wertheim are baseless, and in any event, go to weight, not admissibility. *LG Display Co. v. AU Optonics Corp.*, 265 F.R.D. 199, 207 (D. Del. 2010).

Finally, Liquidia has suffered no prejudice. UTC has repeatedly stated that Liquidia was mischaracterizing Dr. Wertheim's opinions and that he will testify consistently with his Rebuttal Report at trial. Ex. D. Further, Liquidia's contention that "UTC was unwilling to resolve [the FVC] issue" is false and relies on an incomplete recitation of the parties' correspondence which excludes UTC's most recent response. Motion at 2; Ex. E. Liquidia had every opportunity to examine Dr. Wertheim about "FVC" at his deposition but chose not to do so. Any perceived "prejudice" is a problem of Liquidia's own making. Liquidia's Motion should be denied.

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**DEFENDANT’S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE*
REGARDING IMPROVEMENTS IN “FORCED VITAL CAPACITY”
RECITED IN CLAIMS 9 AND 10 OF THE ’327 PATENT**

UTC's Opposition confirms, for the first time in this case, that Dr. Wertheim will testify at trial "that a POSA would understand the term 'forced vital capacity' [(“FVC”)] to encompass **both** the absolute and percent predicted expressions of that endpoint—including in the specific context of claim 9." Opposition, 2 (emphasis in original). This comes after UTC refused to make this confirmation **before** Liquidia served its motion *in limine* (“MIL”). See MIL, Ex. C. Thus, the full scope of claim 9 requires a statistically significant improvement in both absolute (expressed in mL) and percent predicted FVC.

As to UTC's other arguments, Liquidia's MIL regarding FVC presents a different issue than Liquidia's *Daubert* seeking to exclude Dr. Wertheim's opinion that “changes in FVC were correlated with changes in exercise capacity” and that statistical significance for claim 10 is not required for absolute improvements in FVC, because they are not the product of reliable principles or methods nor a reliable application of principles or methods to the facts. See generally D.I. 281. UTC's assertion that this MIL is duplicative of Liquidia's *Daubert* motion to exclude opinions of Dr. Wertheim is thus incorrect and Liquidia did not violate the scheduling order.

UTC also asserts that “[t]he actual target of Liquidia's Motion is Dr. Wertheim's opinion that a POSA would view percent predicted FVC as ‘preferable’ to absolute FVC[.]” Opposition, 3. Liquidia did not argue that in its MIL and instead will cross-examine Dr. Wertheim on this issue in light of the statements in the '327 patent to the contrary, including claim 10, which is limited only to a statistically significant improvement in absolute FVC.

The Court should grant Liquidia's MIL, limiting UTC to its concession, made for the first time in its Opposition, that “that a POSA would understand the term 'forced vital capacity' [(“FVC”)] to encompass **both** the absolute and percent predicted expressions of that endpoint—including in the specific context of claim 9.”

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